AMENDMENT TO THE CLAIMS

The listing of claims below will replace all prior versions and listings of claims in the application:

Listing of Claims:

What is claimed is:

1. (currently amended) A unit dosage form comprising atorvastatin, or a pharmaceutically acceptable salt thereof, and an excipient or combination of excipients, prepared without a granulation step, wherein the measured atorvastatin potency of said dosage form shows a relative standard deviation for atorvastatin potency per unit dosage form of not more than about 7.8%, when said unit dosage form is prepared at a rate greater than 10,000 unit dosage forms per hour per single unit dosage form per machine;
wherein said excipient or combination of excipients comprises greater than about 50 wt% of a diluent or combination of diluents selected from the group of lactose monohydrate, lactose anhydrous, microcrystalline cellulose or sodium chloride; and said excipient or combination of excipients contains less than about 5 wt% of an alkalizing agent additive.
2. (original) The unit dosage form of Claim 1 wherein said unit dosage form is a capsule or tablet and said unit dosage form is manufactured using a capsule filler or tablet press.
3. (cancelled) The unit dosage form of Claim 1 which further comprises an excipient or combination of excipients.
4. (original) The unit dosage form of Claim 1 wherein said atorvastatin or pharmaceutically acceptable salt thereof is a form of atorvastatin that is at least somewhat disordered or a mixture of crystalline and disordered forms of atorvastatin.
5. (cancelled) The unit dosage form of Claim 3 wherein said excipient or combination of excipients contains less than about 5 wt% of an alkalizing agent additive.

6. (currently amended) The unit dosage form of ~~Claim 3~~ Claim 1 wherein said excipient or combination of excipients contains less than about 5 wt% of an alkaline earth metal salt additive.

7. (currently amended) The unit dosage form of ~~Claim 3~~ Claim 1 wherein said excipient or combination of excipients contains less than about 5 wt% of a polymeric amide or polymeric amine additive.

8. (currently amended) The unit dosage form of atorvastatin according to Claim 1 ~~Claims 1-7~~ wherein said unit dosage form contains not more than about 2% total drug related impurities and/or degradants based on the area percent of the impurities and/or degradants relative to the integrated area of all drug related peaks as determined by HPLC.

9. (currently amended) The unit dosage form of atorvastatin according to Claim 1 ~~Claims 1-7~~ wherein said unit dosage form contains not more than about 2% atorvastatin lactone based on the area percent of the lactone peak relative to the integrated area of all drug related peaks as determined by HPLC.

10. (currently amended) The unit dosage form of atorvastatin according to Claim 1 ~~Claims 1-7~~ wherein said unit dosage form, after storage at 40°C and 75% relative humidity for 4 weeks, contains not more than about 1% total drug related impurities and/or degradants based on the area percent of all drug related peaks relative to the area of the atorvastatin peak as determined by HPLC.

11. (currently amended) The unit dosage form of atorvastatin according to Claim 1 ~~Claims 1-7~~ wherein said unit dosage form, after storage at 40°C and 75% relative humidity for 4 weeks, contains not more than about 1% atorvastatin lactone based on the area percent of the lactone peak relative to the integrated area of all drug related peaks as determined by HPLC.

12. (currently amended) The unit dosage form of ~~Claim 3~~ Claim 1, wherein the composition formed from said excipient or combination of excipients and said atorvastatin or a pharmaceutically acceptable salt thereof has a segregation number of less than 0.6 when tested with a fluidization segregation tester.

13. (cancelled) The unit dosage form of Claim 3 wherein said excipient or combination of excipients comprises greater than about 50 wt% of a diluent or combination of diluents.

14. (currently amended) The unit dosage form of ~~Claim 13~~ Claim 1 wherein greater than about 50 wt% of said diluent or combination of diluents has a mean particle diameter between about 80 and 360 μm.

15. (currently amended) The unit dosage form of ~~Claim 13~~ Claim 1 wherein said diluent or combination of diluents has a weighted average segregation number less than about 0.6.

16. (cancelled) The unit dosage form of wherein said diluent is lactose monohydrate, lactose anhydrous, microcrystalline cellulose or sodium chloride.

17 (currently amended) The unit dosage form according to ~~Claim 13~~ Claim 1 wherein said unit dosage form is a tablet or capsule and also contains at least one active drug in addition to the atovastatin.

18. (withdrawn) The unit dosage form according to Claim 17 wherein said active drug in addition to the atorvastatin includes torcetrapib or amlodipine and pharmaceutically acceptable salts thereof.

19. (withdrawn) A method for preparing tablets or capsules of atorvastatin or a pharmaceutically acceptable salt thereof comprising the following steps:

(a) preparing an atorvastatin composition by blending atorvastatin or a pharmaceutically acceptable salt thereof, and one or more excipients suitable for use without a granulation step in a mixer; and

(b) filling a tablet die or capsule and compressing or sealing such that the measured atorvastatin potency shows a relative standard deviation for atorvastatin activity per tablet or capsule of not more than about 7.8% when said tablets or capsules are prepared on a tablet press or capsule filler such that greater than 10,000 tablets or capsules are produced per hour per machine.

20. (withdrawn) The method according to Claim 19 wherein said one or more excipients comprise greater than about 50 wt% of a diluent or combination of diluents.

21. (withdrawn) The method according to Claim 19 or 20 wherein the atorvastatin or pharmaceutically acceptable salt thereof is a form of atorvastatin that is at least somewhat disordered or a mixture of crystalline and disordered forms of atorvastatin.

22. (withdrawn) The method according to Claim 19 wherein said one or more excipients contain less than about 5 wt% of an alkaline earth metal salt additive.

23. (withdrawn) The method according to Claim 19 wherein said one or more excipients contain less than about 5 wt% of an alkalizing agent additive.

24. (withdrawn) The method according to Claim 19 wherein said one or more excipients contain less than about 5 wt% of an amide polymer or amine polymer additive.

25. (withdrawn) The method according to Claim 19 wherein tablets or capsules produced therein have less than about 1 wt% atorvastatin lactone based on the area percent of the lactone peak relative to the integrated area of all drug related peaks as determined by HPLC.

26. (withdrawn) The method according to Claim 20 wherein the combination of said atorvastatin and said diluent or combination of diluents provides a segregation number of less than about 0.6 when tested as a blend in a fluidization segregation tester, and where said diluent or combination of diluents has a mean particle diameter of between about 80 and 360 μm.

27. (withdrawn) The method of preparing a tablet or capsule containing atorvastatin and at least one other active drug wherein the composition prepared according to the method of Claim 19 is combined with at least one other active drug and optionally additional excipients.

28. (withdrawn) A method of treating hypercholesterolemia and/or hyperlipidemia, osteoporosis, benign prostatic hyperplasia, and Alzheimer's disease comprising administering a therapeutically effective dose of atorvastatin unit dosage forms prepared without a granulation step.

29. (withdrawn) A kit for achieving a therapeutic effect in a mammal comprising a therapeutically effective dose of atorvastatin tablets or capsules prepared without a granulation step and a container for containing said unit dosage forms.

30. (withdrawn) The kit according to Claim 29 containing a form of atorvastatin that is at least somewhat disordered or a mixture of crystalline and disordered forms of atorvastatin.